REMARKS/ARGUMENTS

This communication responds to the Office Action of April 10, 2008, and the Advisory Action of September 30, 2008, in which claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-51 are pending.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-51 stand rejected to under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Application Publication No. US 2005/0025756 to Charles Erwin (hereinafter "Erwin"), in view of European Patent Application EP 888 774, to Soft Gel Technologies, Inc. (hereinafter "EP 0 888 774") and U.S. Patent Application Publication No. US 2004/0001874 to Davidson et al. (hereinafter "Davidson").

The rejection is overcome, at least, for the following reasons.

A. Applicant's Declaration under 37 C.F.R. § 1.131 and associated properly exhibits establish "conception of the invention prior to [Erwin's filing date] . . . coupled with due diligence . . . to the filing of the [present] application."

The Examiner claims that Applicant's declarations and exhibits are insufficient to overcome Erwin's priority date, which is 96 days before the filing of the present application. The Examiner states "the evidence submitted with the Declaration does not show reduction to practice of the subject matter of the instant claims before the priority date of Erwin."

1. Applicant's Declaration under 37 C.F.R. § 1.131 and the associated data establishes "conception of the invention prior to [Erwin's effective date] . . ."

Applicant respectfully points out that the Examiner is not relying on the entire and proper standard for Declarations filed under 37 C.F.R. §1.131. A declaration from the inventor may serve to overcome a rejection based on a cited reference(s):

> (b)The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.
> 37 C.F.R. § 1.131 (emphasis added).

Claim 14 recites "[a] soft gelatin capsule, comprising coenzyme Q-10 solubilized in limonene." The Examiner admits that "Applicant prepared several [co Q10 in limonene] solutions." Advisory Action of Sept. 30, 2008. However, the Examiner argues that because "[t]he product was not yet finished," the Declaration was insufficient for failure to show reduction to practice.

Contrary to the Examiner's position, 37 C.F.R. § 1.131 makes clear that evidence may establish either reduction to practice or "conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to . . . the filing of the application."

Applicant has demonstrated conception of the inventive disclosure before the effective date of Erwin. As the M.P.E.P. § 715.07 makes clear:

> [c]onception is the mental part of the inventive act, but it must be capable of proof, as by drawings, complete disclosure to another person, etc. In *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897), it was established that conception is more than a mere vague idea of how to solve a problem; the means themselves and their interaction must be comprehended also.
> M.P.E.P 715.07

Applicant and Examiner agree that conception of the inventive idea was more than "a mere vague idea of how to solve a problem." In Fantuzzi's 2007 and 2008 declarations, a soft gelatin capsule comprising coenzyme Q solubilized in limonene was conceived, at least, by March, 2003. In his 2007 Declaration, Fantuzzi states "a focal point of my research was to find a way to solubilize COQ-10 for the purpose of encapsulating COQ-10 in a soft gelatin capsule" and that on March 13, 2003, "in response to queries from a colleague regarding the solubility of COQ-10, I suggested the use of d-limonene." *Fantuzzi Declaration Dated September 27, 2007* (hereinafter "Fantuzzi 2007 Declaration"). The Examiner admits as much when citing to Applicant's Declaration for stating "that, on March 13, 2003, [Applicant] was given the assignment of identifying a new solvent for co Q10 and of developing a more effective method for encapsulating co Q10 in a soft gel." On March 14, Fantuzzi noted in the laboratory notebook that he "wanted to see what would happen when the solution was added to oil, since pure D-Limonene isn't real practical for a softgel fill," thus evidencing conception of combining coQ10 and limonene in a softgel capsule.

The Examiner improperly discounts conception as the proper standard, stating that "being given an assignment to do a particular task is not at all the same thing as successfully completing that task." 37 C.F.R § 1.131 does not require completion of the task; rather, all that is required is conception prior to the effective date of the reference followed by "due diligence from prior to said date to . . . the filing of the application." Applicant's conception of the presently claimed invention is clearly evidenced by the Fantuzzi 2007 Declaration.

2. Applicant's Declaration under 37 C.F.R. § 1.131 and associated exhibits establish that conception was followed by "due diligence . . . to the filing of the [present] application."

Having established a conception date more than three months before Erwin's effective date, the Applicant is only required to show due diligence to the constructive reduction to practice date of filing the present application. "Where conception occurs prior to the date of the reference, but reduction to practice is afterward, ... applicant must show evidence of facts establishing diligence." M.P.E.P. § 715.07(a).

The facts in the present case demonstrate that the Applicant diligently pursued the inventive concept until filing of the application. With reference to the laboratory notebook pages accompanying the Fantuzzi 2007 Declaration, a number of conditions for combining limonene and CoQ10 were tested. On March 13, 2003, inventor Fantuzzi tested the solubility of CoQ10 in limonine, and determined that it dissolved in limonene after stirring for 2 to 3 minutes. On March 14, 2003 Fantuzzi noted that he was asked to "find a way to further solublize [sic] CoQ10 than the 5% that theoritically could be attained in soybean oil." Fantuzzi further noted that he "wanted to see what would happen when the solution was added to oil, since pure D-Limonene isn't real practical for a softgel fill" (further evidencing the conception of combining coQ10 and limonene in a softgel capsule). After testing a number of different components, Fantuzzi also tested degradation of CoQ10 in limonene.

On March 21, 2003, Fantuzzi tested additional components including tocopherol, rice ban oil, yellow beeswax, and natural beta carotene. On March 26, 2003 Fantuzzi tested CoQ10 and limonene in soybean oil. On May 28, 2003, Fantuzzi noted that limonene is actually dissolving coQ. Then on July 31, 2003, Fantuzzi wrote an email to Patricia Kim and Richard Passwater summarizing the CoQ10 fomulation, the state of continuing solubilization, the quality control

(Q.C.) testing including investigation of oxidation stats of the molecule, and results of vitamin E formulation testing. The instant patent application was filed on September 29, 2003. As evidenced by the Declaration, Applications were diligent in preparing formulations within the scope of the presently claimed invention from conception through filing of the application (i.e. constructive reduction to practice).

In summary, the Applicant has demonstrated that conception took place well before the effective date of Erwin. Applicant was then diligent in reducing the concept to practice through filing of the present application. Therefore, Erwin is not prior art to the instant invention. For at least this reason, the obviousness rejection under 35 U.S.C § 103 based in part on Erwin is improper.

3. Applicant has not made inconsistent statements regarding the state of the art and the present application.

Examiner claims that "in view of the prosecution history, Applicant cannot now assert that the solution is the same thing as the soft gel containing the solution." Examiner characterizes Applicant's position in prior responses as an assertion "that preparing a soft gel containing a solution of co Q10 in d-limonene is not an obvious modification of making that solution."

The Examiner mis-states Applicant's position, and mis-states the requirements for prior art rejections. The non-obviousness of the presently claimed invention is not obvious in view of valid prior art. Valid prior art does not include Applicant's patent application or Applicant's efforts in conception and diligence to make any invention disclosed therein. Moreover, Applicant affirmatively makes no assertion that the combination of the claimed elements was in any way obvious in view of the cited references, whether or not the cited references are validly prior art. Applicant simply has demonstrated that the presently claimed invention was conceived of prior to the effective date of Erwin, and that Applicant diligently developed the technology until constructive reduction to practice. Nothing in Applicant's arguments is inconsistent with Applicant's previous positions.

B. Those of skill in the art would not have been motivated to select and combine elements from the cited references.

Applicant notes that even if Erwin was prior art, which it categorically is not, the cited references in combination do not teach one of ordinary skill in the art how to make a soft gel capsule containing coQ10 and limonene. The presently disclosed composition is capable of solubilizing much greater concentrations of CoQ10 than taught by the cited references. Erwin's priority document, 60/482,781, teaches that the mixture must be heated to 42°C (greater than 105°F) with constant stirring. Erwin as filed teaches that high temperature (42°C) is needed to solubilize CoQ10. Thus, solubilization of coQ10 in limonene as taught by the cited references (as opposed to the present patent application) requires an elevated solubilization temperature. One of skill in the art would hardly be motivated to elevate the temperature of the soft gelatin capsules. One of skill in the art would not be motivated to make the presently claimed invention. For this reason alone the Examiners rejection is in error and should be withdrawn.

C. The cited references do not support a prima facie case of obviousness where there is no reasonable expectation of success.

Assuming and not admitting *in arguendo* that Erwin is prior art, the Examiner has not satisfied the requirements of a prima facie case for obviousness. As stated in the M.P.E.P., "prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success." (M.P.E.P. § 2143.02).

Erwin's priority document, 60/482,781, teaches that the mixture must be heated to 42°C (greater than 105°F) with constant stirring. Erwin as filed teaches that high temperature (42°C) is needed to solubilize CoQ10. Thus, solubilization of coQ10 in limonene as taught by the cited references (as opposed to the present patent application) requires an elevated solubilization temperature. Yet the claim recites a "soft gelatin capsule, comprising coenzyme Q-10 solubilized in limonene." Based on the teachings of the references, one of skill in the art would hardly have a reasonable expectation of success in making the claimed soft gelatin capsule, since such a capsule would require maintaining the temperature of the soft gelatin capsule at greater than 42°C to keep the coenzyme Q10 dissolved in limonene.

CONCLUSION

In accordance with the amendments and arguments set forth herein, the Assignee respectfully submits the application and all claims are in a condition for allowance, and requests such prompt allowance.

This Amendment is filed concurrently with a Request for Continued Examination (RCE) and a Petition for Extension of Time. The applicable fees ($405.00 for the RCE and $865.00 for the extension of time) may be charged to Deposit Account No. 04-1415. The Assignee believes no additional fees or petitions are due with this filing. However, should any additional fees or petitions be required, please consider this as authorization therefor and please charge such fees to Deposit Account number 04-1415.

Should any issues remain that the Examiner believes may be dealt with in a telephone conference, he is invited to contact the undersigned at 303-629-3400.

Dated: April 10, 2009.

Respectfully submitted,

Timothy A. Worrall, Registration No. 54,552
USPTO Customer No. 20686

DORSEY & WHITNEY LLP
370 17th Street, Suite 4700
Denver, Colorado 80202-5647
Telephone: 303-629-3400
Facsimile: 303-629-3450

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